

WE CLAIM:

1. A method for determining a smoothness index of a metered dose

5 container having an inner core comprising the steps of

a) subjecting said inner core of said metered dose container to reflected light photomicrography to obtain a digital image containing a plurality of pixels of said inner core;

b) determining from said digital image the brightness of each of  
10 said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness; and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said inner core of said metered dose container.

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2. A method for determining a smoothness index of a metered dose

container having an inner core comprising the steps of

a) subjecting said inner core of said metered dose container containing at least one pharmacologically active agent to reflected light  
20 photomicrography to obtain a digital image containing a plurality of pixels of said inner core;

b) determining from said digital image the brightness of each of said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness; and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said inner core of said metered dose container.

5     3.     The method for determining a smoothness index of a metered dose container having an inner core according to claim 2, wherein the at least one pharmacologically active agent is a corticosteroid.

4.     The method for determining a smoothness index of a metered dose  
10    container having an inner core according to claim 3, wherein the corticosteroid is selected from the group consisting of mometasone furoate anhydrous; beclomethasone dipropionate; budesonide; fluticasone; dexamethasone; flunisolide; triamcinolone; (22R)-6 $\alpha$ , 9 $\alpha$ -difluoro-11 $\beta$ ,21-dihydroxy-16 $\alpha$ ,17 $\alpha$ -propylmethylenedioxy-4-pregnen-3,20-dione; and tipredane.

15    5.     The method for determining a smoothness index of a metered dose container having an inner core according to claim 4, wherein corticosteroid is mometasone furoate anhydrous.

20    6.     The method for determining a smoothness index of a metered dose container having an inner core according to claim 4, wherein the corticosteroid is beclomethasone dipropionate.

7. The method for determining a smoothness index of a metered dose container having an inner core according to claim 4, wherein the corticosteroid is budesonide.

5 8. The method for determining a smoothness index of a metered dose container having an inner core according to claim 4, wherein the corticosteroid is fluticasone.

9. The method for determining a smoothness index of a metered dose  
10 container having an inner core according to claim 2, wherein the at least one pharmacologically active agent is a  $\beta$ -agonist.

10. The method for determining a smoothness index of a metered dose container having an inner core according to claim 9, wherein the  $\beta$ -agonist is  
15 selected from the group consisting of albuterol, terbutaline, salmeterol, bitolterol, formoterol, eFormoterol, 2(1H)-Quinolinone, 8-hydroxy-5-[1-hydroxy-2-[[2-(4-(methoxyphenyl)-1-methylethyl]amino)ethyl]-monohydrochloride, [R-(R\*,R\*)]-.

11. The method for determining a smoothness index of a metered dose  
20 container having an inner core according to claim 10, wherein  $\beta$ -agonist is albuterol.

12. The method for determining a smoothness index of a metered dose container having an inner core according to claim 10, wherein the  $\beta$ -agonist is terbutaline.

5 13. The method for determining a smoothness index of a metered dose container having an inner core according to claim 10, wherein  $\beta$ -agonist is formoterol.

14. The method for determining a smoothness index of a metered dose  
10 container having an inner core according to claim 10, wherein the  $\beta$ -agonist is salmeterol.

15. The method for determining a smoothness index of a metered dose container having an inner core according to claim 2, wherein the at least one  
15 pharmacologically active agent is selected from the group consisting of ipratropium bromide, oxitropium bromide, sodium cromoglycate, nedocromil sodium, montelukast, zafirlukast, pranlukast, bambuterol, fenoterol, clenbuterol, procaterol and broxaterol.

20 16. The method for determining a smoothness index of a metered dose container having an inner core according to claim 15, wherein the at least one pharmacologically active agent is montelukast.

17. The method for determining a smoothness index of a metered dose container having an inner core according to claim 2, wherein the at least one pharmacologically active agent is selected from a combination of a corticosteroid and a  $\beta$ -agonist.

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18. The method for determining a smoothness index of a metered dose container having an inner core according to claim 17, wherein the corticosteroid is mometasone furoate anhydrous and the  $\beta$ -agonist is formoterol.

10 19. The method for determining a smoothness index of a metered dose container according to claim 17, wherein the corticosteroid is budesonide and the  $\beta$ -agonist is terbutaline.

20. The method for determining a smoothness index of a metered dose  
15 container having an inner core according to claim 17, wherein the corticosteroid is fluticasone and the  $\beta$ -agonist is salmeterol.